

Doc Code: AP.PRE.REQ

PTO/SB/33 (07/05)

Approved for use through xx/xx/200x. OMB 0651-00xx

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

**PRE-APPEAL BRIEF REQUEST FOR REVIEW**

Docket Number (Optional)

ACSES 52008 (G1816USO1)

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR

on SEPTEMBER 4, 2007

Signature

Typed or printed  
nameTHOMAS H. MAJCHER

Application Number

09/476,689

Filed

December 30, 1999

First Named Inventor

Kent C.B. Stalker

Art Unit

3764

Examiner

Phillip A. Gray

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).

Note: No more than five (5) pages may be provided.

I am the

☐ applicant/inventor.☐ assignee of record of the entire interest.  
See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.  
(Form PTO/SB/96)☒ attorney or agent of record.Registration number 31,119☐ attorney or agent acting under 37 CFR 1.34.

Registration number if acting under 37 CFR 1.34 \_\_\_\_\_

Signature

THOMAS H. MAJCHER

Typed or printed name

310 824 5555

Telephone number

SEPTEMBER 4, 2007

Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below\*.

☐ \*Total of \_\_\_\_\_ forms are submitted.

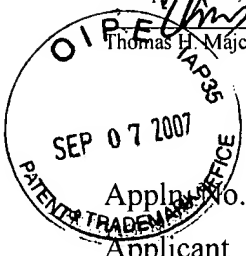
This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to: MAIL STOP APPEAL BRIEF-PATENTS, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on September 4, 2007

Thomas H. Majcher, Reg. No. 31,119



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant No. : 09/476,689 Confirmation No. 8160

Applicant : Kent C.B. Stalker

Filed : December 30, 1999

Art Unit : 3764

Examiner : Gray, Phillip A

Title : DEVICE FOR, AND METHOD OF, BLOCKING EMBOLI IN  
VESSELS SUCH AS BLOOD ARTERIES

Docket No.: : ACSES 52008 (G1816USO1) Los Angeles, California

Customer No. : 24201 September 4, 2007

MAIL STOP APPEAL BRIEF-PATENTS

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

PRE-APPEAL BRIEF REQUEST FOR REVIEW

INTRODUCTION

The presently claimed invention is directed to a filtering device for trapping and removing emboli from a body vessel (e.g. an artery). The filtering device can be placed in the body vessel at a position downstream from a lesion formed within the vessel to trap any emboli that might be generated when an interventional procedure is being performed on the lesion. The filtering device includes a directional member made from a pliable material having properties of blocking fluid and emboli passage and being expandable by the fluid flow in the body vessel. The pliable material does not possess self-expanding properties, i.e., the directional member is not made from a self-expanding material, such as Nitinol, and solely relies on the fluid pressure to expand the pliable material into the expanded position. Due to its ability to block the passage of fluid, the directional member is designed to direct the fluid and any emboli into the filtering member, which is attached to the directional member.

The filtering member is made from a material which blocks the passage (filters) of emboli in the fluid. The directional member is designed to create a deep pocket which is used to trap the emboli while allowing the fluid to pass there through to downstream vessels. In the presently claimed invention, the directional member has a truncated conical shape when expanded which acts much like a "wind sock" when deployed in the fluid flow. The directional member opens up when subjected to the fluid flow and remains in a fully deployed position to partially occlude the vessel, due to fluid build proximal to the directional member. The filtering member located within the deep pocket formed by the directional member provides the filtering media for trapping the emboli. In this fashion, the directional member is designed to channel all fluid and emboli into the deep pocket to allow the filtering member to perform the necessary filtration. The design of the deep pocket helps to retain the emboli deep within the filtering device, sufficiently past the inlet opening of the directional member. As a result, there is a less possibility that trapped emboli will "backflow" into the artery as the filtering portion of the device is being collapsed and removed from the patient's vasculature.

#### NOTICE OF APPEAL

A Notice of Appeal from the Office Action of June 5, 2007 is being filed concurrently herewith along with the appropriate fee. All of the claims have been at least twice rejected.

#### ISSUES ON APPEAL

At issue is whether claims 23-44 are anticipated under 35 U.S.C. § 102(e) by U.S. Patent No. 6,336,934 to Gilson et al. (the "Gilson patent").

The Gilson patent discloses a number of embolic protection devices having a collapsible filter element mounted to the distal end portion of a catheter. The Examiner has taken the position that the Gilson patent discloses the directional member having the properties and structure recited in the present claims. However, Applicant believes that the Examiner has erred in construing the claims, along with misconstruing the specific structures appearing in the Gilson patent. Moreover, the Examiner has taken inconsistent position regarding the structure in the Gilson patent that he considers to constitute the directional members.

A copy of the pending claims is attached hereto as Exhibit A. A copy of the drawings is attached hereto as Exhibit B. A copy of the final Office Action dated June 5, 2007 is attached hereto as Exhibit C. A copy of the Gilson patent is attached as Exhibit D.

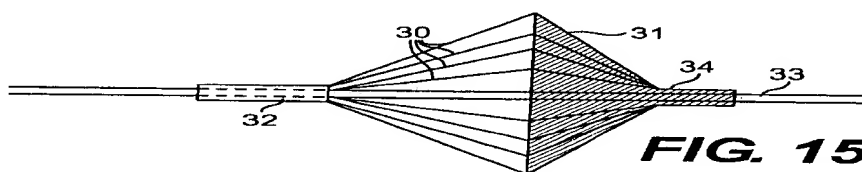
## ARGUMENT

Claims 23-44 were rejected under 35 U.S.C. § 102(e) as being anticipated by the Gilson patent. All of the pending claims include the recitation of a directional made from a pliable material having properties of blocking the passage of the fluid and the emboli and being expandable by the fluid flow in the body vessel to form a truncated conical shape when placed in an expanded position.

Applicant respectfully disagrees with the Examiner's position regarding the specific disclosure of the Gilson patent. The Examiner has taken the position that:

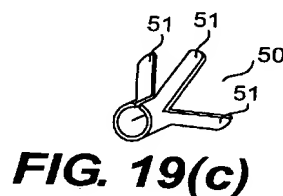
.....the directional and filtering members are in a "truncated conical shape," as shown in figures 40, 19C and figures 14 and 15 (directional members 30 and filter element 31). Gilson shows that the directional member/filter element would have a "truncated conical shape" when in an expanded position. (Office Action dated June 5, 2007, EXHIBIT C) Applicant notes that the Examiner has taken the position that the combination of the directional member and filtering member have a truncated conical shape. The Examiner's position is incorrect since each of the pending claims calls for only the directional member to have the truncated conical shape. Moreover, the embodiments in the Gilson patent relied upon by the Examiner, namely, the devices shown in Figures 40, 19C, 14 and 15 clearly do not have a directional member having the properties of blocking the passage of fluid and certainly do not have a truncated conical shape when expanded. Therefore, for at least this reasons alone, the Gilson patent fails to disclose the particular structure recited in the pending claims.

The Examiner has taken the position that the wire 30 appearing in Figure 15 constitutes a directional member. However, in order to constitute a directional member, these wires have to have the properties of blocking the passage of fluid flow. These wires 30 do not block fluid flow since fluid must pass around each individual wire in order to reach the filter 31. For at least this single reason alone, these wires do not constitute a directional member. Moreover, as can be clearly seen in Figure 15, the arrangement of wires 30 do not create a truncated conical shape.



Accordingly, it is Applicant's position that these wires do not, and cannot, constitute a directional member. Moreover, it is noted that later in the Office Action, the Examiner takes an inconsistent position regarding these wires 30. In rejecting claims 28, 32-34 and 40-43, which require, *inter alia*, a plurality of restraining members, the Examiner changes position regarding these wires 30. Now, the Examiner identifies them as the plurality of restraining wires 30 and identifies the directional member as the component identified by reference numeral 34 (See page 5, lines 12-16). This component is identified as a fixed tube 34 in the Gilson patent. Clearly, this fixed tube 34 do not meet the structural recitations of the directional member recited in the pending claims. More importantly, it clearly shows that the Examiner's position that these wires 30 constitute a directional member has been inconsistent and incorrect.

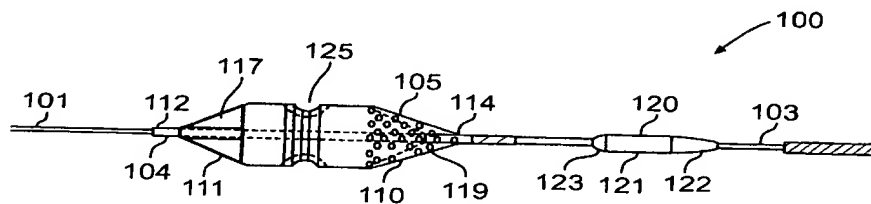
The Examiner also has taken the position that the component identified as a support element 50 in Figure 19 (c) of the Gilson patent constitutes a directional member. Applicant strongly disagrees with the Examiner's position. Figure 19(c) is reproduced below.



Clearly, this support element 50 is made from individual "wings" which open up once deployed. However, like the wires 30, this component allows fluid to flow around each wing to reach the filtering portion of the device. Moreover, the support element 50 must form a truncated conical shape. Given the open wing-like shape of this support element 50 in its expanded position, it does form a conical shape, no less a truncated conical shape. For these reasons, this structure relied upon by the Examiner does not constitute a directional member as presently recited in the pending claims.

Lastly, the Examiner believes that the structure depicted in Figure 40 of the Gilson patent constitutes a truncated conically shaped directional member. At page 4, lines 8-11 of the June 5, 2007 Office action, the Examiner indicates that the filtering portion (105) includes

a directional member (50). However, as can be seen in Figure 40, reproduced below, there is no



**FIG. 40**

element identified with the reference numeral 50. Moreover, the only portion of the device that even has a conical shape is the distal portion where distal outlet openings 119 are formed. However, all of the claims call for the directional member, not the filtering member, to have a truncated conical shape. Applicant submits that the filter device shown in Figure 40 fails to disclose a directional member as is recited in the pending claims.

In summation, the Gilson patent fails to disclose the basic elements recited in the pending claims. The Examiner has misconstrued the claim language and has misconstrued the structure appearing in the Gilson patent.

Respectfully submitted,

FULWIDER PATTON LLP

By:

/Thomas H. Majcher/

Thomas H. Majcher, Reg. No. 31,119

CLAIMS:

1 – 22 (Canceled)

23. (Previously Presented) A filtering device for blocking the passage of emboli through a body vessel, comprising:

a filtering portion including a directional member made from a pliable material having properties of blocking the passage of the fluid and the emboli and being expandable by the fluid flow in the body vessel, wherein the pliable material does not have self-expanding properties; and

a filtering member attached to the directional member and made from a material to block the passage of the emboli, the filtering member being expandable by the expansion of the directional member, wherein the directional member has a truncated conical shape when placed in an expanded position.

24. (Previously Presented) The filtering device of claim 23, wherein:  
the filtering member is made from a material selected from a group consisting of blood filter material and a braided/woven biocompatible material.

25. (Previously Presented) The filtering device of claim 23, further including:  
an elongate tubing adapted to allow an interventional device to be advanced over it to position the interventional device within the body lumen, the elongate tubing having a lumen extending therethrough, wherein the filtering portion and filtering member are disposed in the lumen in a delivery position.

26. (Previously Presented) The filtering device of claim 25, further including:  
a shaft member slidably disposed in the lumen of the elongate tubing for moving the filtering portion and filtering member out of the lumen of the elongate tubing.

27. (Previously Presented) The filtering device of claim 23, wherein:

the directional member is elongated to be disposed against the vessel wall and is disposed relative to the filtering member to direct fluid and the emboli into the filtering member.

28. (Previously Presented) The filtering device of claim 25, further including:

a plurality of restraining wires attached to the directional member and extending along the length of the elongate member, the restraining wires being retractable from a location outside the body vessel to collapse the directional member.

29. (Previously Presented) The filtering device of claim 23 wherein:

the directional member directs body fluid into the filtering member.

30. (Canceled)

31. (Previously Presented) A filtering device for blocking the passage of emboli through a body vessel, comprising:

an elongate tubing having a proximal end and a distal end, the elongate tubing having an outer surface and a lumen extending therethrough and being adapted to have interventional devices advanced over the outer surface to position an interventional device within the body vessel;

a filtering portion including a filtering member made from a material to filter emboli entrained in the body fluid of the vessel and a directional member attached to the filtering member for directing body fluid and emboli into the filter member, the directional member being made from a pliable material having properties of blocking the passage of the fluid and the emboli and being expandable by the fluid flow in the body vessel to form a truncated conical shape when placed in an expanded position, the filtering portion being stored within the lumen of the elongate tubing in a delivery configuration; and



a shaft member movable within the lumen of the elongate tubular for moving the filtering portion and filtering member out of the lumen.

32. (Previously Presented) The filtering device of claim 31, wherein:

the elongate tubing includes a plurality of restraining wires attached to the filtering portion and extending along the length of the tubing, the restraining wires being retractable from a location outside the body vessel to collapse the filtering portion.

33. (Previously Presented) The filtering device of claim 32, wherein:

the filtering member has an inlet opening and the restraining wires are retractable to draw at least the inlet opening of the filtering member into a recovery sheath.

34. (Previously Presented) The filtering device of claim 32, wherein:

the plurality of restraining wires extending within the lumen of the elongate tubing.

35. (Previously Presented) The filtering device of claim 31, wherein:

the shaft member contacts the interior of the filtering member to move the filtering portion and filtering member out of the lumen of the elongate shaft.

36. (Canceled)

37. (Previously Presented) A filtering device for blocking the passage of emboli through a body vessel, comprising:

an elongate tubing having a proximal end, a distal end, and a lumen extending from the distal end to the proximal end, the elongate tubing adapted to have an interventional device advanced over it to position the interventional device within the body vessel;

means for filtering emboli from the fluid in the body vessel, said means being disposed within the lumen of the elongated tubing in a delivery position, said filtering means including a filtering member and a directional member attached to the filter member for directing body fluid

and emboli into the filtering member, the directional member being made from a pliable material having properties of blocking the passage of the fluid and the emboli and being expandable by the fluid flow in the body vessel to form a truncated conical shape when placed in an expanded position; and

means for deploying the filtering means from the lumen into the body vessel.

38. (Previously Presented) The filtering device of claim 37, wherein:

the deploying means is a shaft member movable within the lumen of the elongate tubing for moving the filtering means out of the lumen of the elongate tubing.

39. (Previously Presented) The filtering device of claim 37, further including:

means for retracting the filtering means at least partially back into the lumen.

40. (Previously Presented) The filtering device of claim 39, wherein:

the retraction means includes at least two wire members connected to the filtering means.

41. (Previously Presented) A filtering device for blocking the passage of emboli through a body vessel, comprising:

an elongate tubing having a proximal end, a distal end and a lumen extend from the proximal end to the distal end, the elongate tubing being adapted to have an interventional device advanced over it to position the interventional device within the body vessel;

a plurality of wires disposed within the lumen of the elongate tubing;

a filter coupled to at least two of the plurality of wires, the filter being adapted to filter material from the body vessel and including a filter member and a directional member attached to the filter member for directing body fluid and emboli into the filter member, the directional member being made from a pliable material having properties of blocking the passage of the

fluid and the emboli and being expandable by the fluid flow in the body vessel to form a truncated conical shape when placed in an expanded position; and

means for preventing the plurality of wires from extending outwardly from the lumen until the filter is to be deployed in the body vessel.

42. (Previously Presented) The filtering device of claim 41, wherein:  
the plurality of wires extends outwardly from the lumen when the filter is deployed.

43. (Previously Presented) The filtering device of claim 41, wherein:  
the plurality of wires holds the filter open when the filter is deployed.

44. (Previously Presented) The filtering device of claim 41, further including:  
a shaft member slidably disposed within the lumen of the elongate tubing to move the filter out of the lumen.

194592.1